

### REMARKS

Claims 43, 47-71 and 78 have been rejected as failing to comply with the written description requirement. This rejection is moot as to claims 47-71 and 78. The Examiner asserts that the limitation "the off-axis movement alone being capable of acting to cut tissue" is not supported in the application:

The off-axis movement is not the only force causing the cutting of the tissue. For example, one would have to hold the device against tissue. Applicant further repeatedly states how the device must shear the tissue between the cutter and a surface of the instrument, etc. Therefore, it is clear it is "not alone" and is merely one of several components involved in cutting tissue. See page 2 of Final Office Action.

Applicants disagree. The claim requires that an off-axis *movement*, not an off-axis force, alone be capable of acting to cut tissue. While many forces may be involved in the cutting action (including, for example, shearing forces, such as those between the cutter and a surface of the instrument, and positioning forces, such as those required to maintain the cutter in contact with the tissue), only a single *movement*, i.e., the off-axis movement, of the cutter is capable of acting to cut tissue. Therefore, applicants request reconsideration and withdrawal of the rejection of claim 43.

Claims 72-75 have been rejected as failing to comply with the written description requirement. This rejection is moot in view of the amendment to claim 72.

The pending claims have been rejected as being anticipated by Hamlin (WO 92/108416). Independent claim 1, as amended, recites that the coupling of the cutter to the outer member restrains the cutter from following the rotation of the inner member. In contrast, in Hamlin, the coupling between cutter sheath 46, connector elbow 30, and outer tube 22 (which together the Examiner equates to the recited outer member), and cutter shaft 52 (which the Examiner apparently equates to the recited cutter), does not restrain the cutter shaft 52 from following the rotation of drive shaft 70 (which the Examiner equates to the recited inner member). Rather, the cutter shaft 52 and the drive shaft 70 are linked via gear teeth 68 and 80 such that the cutter shaft 52 follows the rotation of the drive shaft 70.

For at least this reason, applicants request reconsideration and withdrawal of the rejection of claim 1 and its dependent claims.

Independent claim 37 recites a cutter that (1) includes an extended portion extending distal of a terminal end of an outer member to which the cutter is coupled, and (2) is configured and arranged to perform end-on cutting by shearing tissue between a surface of the cutter and another surface of the tissue cutting instrument. The cutter shaft 52 of Hamlin does not include an extended portion that extends distal of a terminal end of the sheath 46. Rather, as shown in Figs. 3 and 4 of Hamlin, the cutter shaft 52 is received in the sheath 46 such that the terminal end of sheath 46 is distal of the cutter shaft 52. Moreover, the cutter shaft 52 is not configured and arranged to perform end-on cutting. Rather, the cutter shaft 52 cuts in a lateral direction. See page 7, lines 29-33.

For at least these reasons, applicants request reconsideration and withdrawal of the rejection of claim 37 and its dependent claims.

Independent claim 47, as amended, recites that during the off-axis movement of the cutter, a cutting edge of the cutter intersects an axis of rotation of the inner member. In Hamlin, rather than intersecting an axis of rotation of the drive shaft 70 during the rotational movement of the cutter shaft 52, the cutting edges of the mouth 64 of the cutter shaft 52 are spaced from the axis of rotation of the drive shaft 70.

For at least this reason, applicants request reconsideration and withdrawal of the rejection of claim 47 and its dependent claims.

Independent claim 72, as amended, recites a cutter defining a through bore having an axis extending between open ends of the through bore and that includes first and second protruding shafts located 180° apart from each other along an outer surface of the cutter, the shafts being aligned transverse to the through bore axis. In Hamlin, proximal end portion of cutter shaft 52, which the Examiner equates to the recited first shaft, and distal end portion 56 of cutter shaft 52, which the Examiner equates to the recited second shaft, are not aligned transverse to a through bore axis of a through bore defined by the cutter shaft 52. Rather, as shown in Fig. 4 of Hamlin, the proximal and distal end portions of cutter shaft 52 themselves define the openings of the through bore of the cutter shaft 52 and, accordingly, are located on the axis extending between the open ends, rather than located transverse to the axis. For at least this reason, applicants request reconsideration and withdrawal of the rejection of claim 72, and its dependent claims.

Applicant : Philip B. Sample  
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According to new claim 80, a passage of the cutter and the axis of rotation of the inner member are axially alignable during the off-axis movement of the cutter. The Hamlin device is not capable of being axially aligned as claimed.

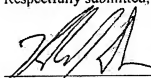
Applicants submit that all claims are in condition for allowance.

The Request for Continued Examination fee of \$810 are being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization. Please apply any other charges or credits to Deposit Account 06-1050.

Respectfully submitted,

Date: \_\_\_\_\_

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Robert J. Devoto  
Reg. No. 55,108

Fish & Richardson P.C.  
1425 K Street, N.W.  
11th Floor  
Washington, DC 20005-3500  
Telephone: (202) 783-5070  
Facsimile: (202) 783-2331